

K120185

**510(k) SUMMARY**

MAY 11 2012

**SUBMITTER:** Sorin Group Italia S.r.l.  
86, Via Statale 12 Nord  
41037 Mirandola (MO) Italy

**CONTACT PERSON:** Luigi Vecchi  
Phone: 011 39 0535 29811  
Fax: 011 39 0535 25229

**DATE PREPARED:** May 08, 2012

**DEVICE TRADE NAME:** INSPIRE 6F hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiectomy reservoir

**COMMON NAMES:** Hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiectomy reservoir  
Hollow Fiber Oxygenator with integrated arterial filter  
Hardshell Venous/Cardiectomy Reservoir

**CLASSIFICATION NAMES:** Cardiopulmonary Bypass Oxygenator/  
Cardiopulmonary Bypass Heat Exchanger/  
Cardiopulmonary Bypass Blood Reservoir/  
Cardiopulmonary Bypass Defoamer/  
Cardiopulmonary Bypass Arterial Line Blood Filter

**PREDICATE DEVICE:** D905 EOS: hollow fiber oxygenator with integrated hardshell venous/cardiectomy reservoir (K043323)

D733 MICRO 40 Ph.I.S.I.O. Arterial Filter:  
Sorin D733 MICRO 40 Arterial Filter with 40 micron screen with phosphorylcholine coating (K112525)

**DEVICE DESCRIPTION:**

The INSPIRE 6F is consisting of an oxygenator, integrated with an arterial filter and a heat exchanger (INSPIRE 6F M), and a hardshell venous/cardiectomy reservoir (INSPIRE HVR). The reservoir is connected to the gas exchange module by means of a molded fitting joint.

The INSPIRE 6F is a high efficiency microporous hollow fiber membrane oxygenator, integrated with an arterial filter and a heat exchanger, connected to a hardshell venous/cardiectomy reservoir.

The device can be operated at flow rates up to 6 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The integrated arterial filter provides additional protection against air and solid emboli and the integrated hardshell reservoir collects, defoams, filters venous and suction blood, and can be used post-operatively for chest drainage.

The INSPIRE 6F is a modified version of the currently marketed integrated oxygenator/hardshell venous cardiotomy reservoir system (D905 EOS) and of the arterial filter (D733 MICRO 40 Ph.I.S.I.O., hereinafter referred to as D733) respectively in commercial distribution as separate units.

#### **INDICATION FOR USE:**

The intended use for the two elements that constitute the integrated device are:

##### INSPIRE 6F M: Hollow Fiber Oxygenator

INSPIRE 6F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 6F M is intended to be used for 6 hours or less.

##### INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir

INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage. INSPIRE HVR is intended to be used for 6 hours or less.

#### **TECHNOLOGICAL CHARACTERISTICS:**

The INSPIRE 6F has the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate devices.

Sorin believes that the INSPIRE 6F is substantially equivalent to the D905 EOS on the basis of operating principles and basic function. The integrated arterial filter of INSPIRE 6F is also substantially equivalent to the D733 predicate device with respect to the expected main function of an arterial filter.

The INSPIRE 6F and the predicate devices share the same fundamental technological characteristics except for some modifications that do not affect the basic device function. Any differences do not raise any new issues of safety and effectiveness.

The INSPIRE 6F is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

#### **NON CLINICAL TEST RESULTS:**

Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

**IN VITRO TEST RESULTS:**

In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff" issued on November 13, 2000, "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000; "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000; ISO 15675 "Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters" and ISO 15674, "Cardiovascular implants and artificial organs — Hard-shell cardiectomy/venous reservoir systems (with/without filter) and soft venous reservoir bags".

In vitro testing was carried out to demonstrate both the substantial equivalence with the predicate device and also to comply with safety and effectiveness requirements. Testing supplied in the 510(k) premarket notification includes performance tests and mechanical integrity tests that demonstrate compliance with performance specifications.

The tests that were performed are listed in the following summary table. The INSPIRE 6F passed each test mentioned in the table below.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Physical/Mechanical	Structural Integrity
2	Physical/Mechanical	Blood, water, gas pathway integrity
3	Physical/Mechanical	Blood pathway integrity
4	Functional/Performance	Blood volume capacity
5	Functional/Performance	Blood rest volume
6	Functional/Performance	Gas transfer performance/blood side pressure drop
7	Functional/Performance	Heat exchange performance/water side pressure drop
8	Functional/Performance	Air handling capability
9	Functional/Performance	Air handling
10	Functional/Performance	Break-through time and volume
11	Functional/Performance	Defoaming efficiency
12	Functional/Performance	Dynamic priming volume / Hold-up
13	Functional/Performance	Filtration Efficiency
14	Functional/Performance	Filtration Efficiency - venous section
15	Functional/Performance	Filtration Efficiency - cardiectomy section
16	Functional/Performance	Flow rate capacity
17	Functional/Performance	Pressure drop
18	Functional/Performance	Hemolysis

TEST	TEST CLASSIFICATION	TEST TITLE
19	Functional/Performance	Reservoir Hemolysis
20	Functional/Performance	Blood compatibility
21	Functional/Performance	Reservoir Blood compatibility
22	Functional/Performance	Leaching of coating
23	Functional/Performance	Reservoir Leaching of coating
24	Functional/Performance	Flaking of coating
25	Functional/Performance	Reservoir Flaking of coating
26	Functional/Performance	Uniformity of coating

#### **CONCLUSIONS:**

The results of in vitro studies demonstrate that the INSPIRE 6F performs in a manner substantially equivalent to the D905 EOS predicate device with respect to the relevant functional parameters. Also, the INSPIRE 6F performs in a manner substantially equivalent to the D733 predicate device, with respect to the filtering and air handling performances. Test results of this study suggest the INSPIRE 6F is equivalent to the predicate devices with respect to device function.

Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

MAY 11 2012

Sorin Group Italia s.r.l.  
c/o Mr. Barry Sall  
Principal Consultant  
Parexel International Consulting  
195 West Street  
Waltham, WA 02451

Re: K120185

Trade/Device Name: Inspire 6F Hollow Fiber Oxygenator with Integrated Arterial Filter and  
Hardshell Venous Cardiotomy/Reservoir  
Regulation Number: 21 CFR 870.4350  
Regulation Name: Cardiopulmonary Bypass Oxygenator  
Regulatory Class: Class II  
Product Code: DTZ  
Dated: May 8, 2012  
Received: May 9, 2012

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

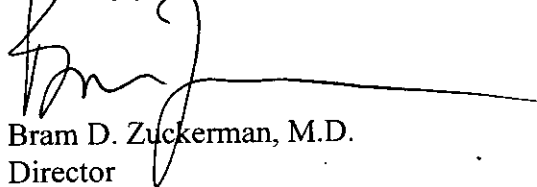
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Bram D. Zuckerman', followed by a long horizontal line extending to the right.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K120185

Device Name: INSPIRE 6F Hollow Fiber Oxygenator with integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir:

### Indications for Use:

#### INSPIRE 6F M: Hollow Fiber Oxygenator

INSPIRE 6F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 6F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 6F M is intended to be used for 6 hours or less.

#### INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir

INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage. INSPIRE HVR is intended to be used for 6 hours or less.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number

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